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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/209,125 12/10/98 AIYAR

J PHM.70293-US

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HM12/0330

EXAMINER

BASILIN

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

03/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/209,125

Applicant(s)

AIYAR et al

Examiner

Nirmal. S. Basi

Group Art Unit

1646

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-30 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-30 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1646

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646.

5 **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula
10 Hutzell, Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- 15 I. Claim 6, drawn to a purified peptide comprising the amino acid sequence substantially as depicted in SEQ ID NO:3, classified in class 530, subclass 350.
- II. Claims 1-5 and 8-9, drawn to the polynucleotide sequence encoding the polypeptide of SEQ ID NO:3 or comprising SEQ ID NO:2, fragments thereof, vectors encoding, cells containing the afore mentioned expression vectors and a method of production

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and recovery of the of the encoded protein of SEQ ID NO:3 from said cells, classified in class 536, subclass 23.1, for example .

III. Claim 4, drawn to antisense molecule comprising the complement of the polynucleotide of claim 2, classified in class 536, subclass 24.5, for example .

5 IV. Claims 7 and 28, drawn to a antibody, classified in class 530, subclass 387.9, for example.

V. Claims 10-13 drawn to a method of identifying compounds that modulate the biological activity of a potassium channel using the polypeptide represented by SEQ ID NO:3 , classified in class 435, subclass 7.1 for example.

10 VI. Claims 14-21, drawn to compositions identified by Invention V, classified and subclass can not be determined because compositions have not be identified.

VII. Claims 22-25 drawn to method of treatment using the compositions of Group VI, classified and subclass can not be determined because compositions have not be identified.

15 VIII. Claims 26 and 27 drawn to method of treatment using an antisense molecule of claim 4, classified in class 514, subclass 44 for example.

IX. Claim 29 drawn to diagnostic compositions comprising PCR primers derived fro SEQ ID NO:1, classified in class 536, subclass 24.33 for example.

20 X. Claim 29 drawn to diagnostic compositions comprising PCR primers derived fro SEQ ID NO:1, classified in class 536, subclass 24.33 for example.

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The inventions are distinct, each from the other because of the following reasons:

5 The proteins of Invention I are related to the nucleic acids of Invention II by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in claim 9. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for the processes other than the production of the protein, such as
10 nucleic acid hybridization.

The methods of Inventions II are related to the proteins of Invention I as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In
15 the instant case the product as claimed may be isolated from its natural source or made by chemical peptide synthesis.

The proteins of Invention I are related to antibodies of Invention IV by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary steric complementary of the two, they are distinct inventions
20 because they are physically and functionally distinct chemical entities, and because the protein can be

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used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right or in assays for the identification of agonists of the potassium channel.

5 The products of Inventions I-IV, VI and IX-X are distinct from each other because they have distinct functional, chemical and physical properties.

The proteins Inventions I and the methods of Inventions V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins may be used for the production of antibodies of Invention IV.

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The products of Inventions II-IV and IX-X are distinct from the method of Invention V and VII wherein the products of Invention II-IV can neither be used in nor made by the method of Invention V and VII.

15 The products Inventions VI and the methods of Inventions V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins may be used for the production of antibodies of Invention IV.

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The methods of Inventions II, V, VII-VIII are distinct from each other because they are independent, using separate method steps, active agents and having different effects.

Inventions II and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides may be used for the production of proteins.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper. A search of the art for Inventions I-X would not be co-extensive with each other as shown by their different classifications. Because the searches required for these inventions are not co-extensive an examination of the materially different, patentably distinct inventions in a single application would constitute a serious burden on the examiner.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Thursday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
March 23, 2000

Gary L. Kunz
GARY L. KUNZ
PRIMARY EXAMINER
GROUP 1200